IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: **WAVE 3 CASES LISTED IN EXHIBIT A TO DEFENDANTS' MOTION**	

MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE GENERAL-CAUSATION TESTIMONY OF NEERAJ KOHLI, M.D., M.B.A.

Neeraj Kohli, M.D. seeks to offer various opinions regarding TVT-O, including its design and marketing history, surgical technique, alleged design defects, complications, warnings, and physician training. Defendants Ethicon, Inc., Johnson & Johnson, and, if applicable, Ethicon LLC (Ethicon) ask that certain of these opinions are inadmissible under this Court's own rulings, Rules 702 and 403, and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). They are:

- **Opinions criticizing the surgical technique to support design defect**. These opinions are inadmissible to prove a design defect because an alternative *surgical procedure* is not an alternative *design*.

- **Opinion claiming that TVT-O's complication rates and severity are "unacceptably high."** Dr. Kohli identifies no reliable methodology for determining what constitutes "unacceptably high" and instead offers only his *ipse dixit* and personal opinions as to what is "unacceptably high."

- **Opinion that clinical studies would have demonstrated "flaws" in TVT-O.** What hypothetical clinical studies would have shown is nothing but speculation, and not good science.

- **Opinion regarding TVT-O's appropriateness for certain patient populations.** Dr. Kohli offers no support for this opinion.

- **Opinions regarding the competency of other physicians.** These opinions are not only irrelevant, but also speculative and misleading.

- **Opinions relating to Ethicon's motives, knowledge, and intent.** This Court has repeatedly excluded this testimony so it should be excluded here.

As more fully established below, these opinions should be excluded.

ARGUMENTS AND AUTHORITIES

Ethicon incorporates by reference the standard for *Daubert* motions articulated by the Court in *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at *1-3 (S.D.W. Va. July 8, 2014).

I. Dr. Kohli's surgical-technique design-defect opinions should be excluded as irrelevant.

Dr. Kohli will testify that various aspects of the TVT-O *surgical technique* make the TVT-O defective in design. Ex. B, Kohli Report at 8-9. Meanwhile, he admits that the product he currently uses—TVT—is comprised of the exact same polypropylene mesh as the product he criticizes here—TVT-O. Ex. C, Kohli 3/21/16 Dep. Tr. 38:5-10 (testifying that he currently implants TVT); *id.* at 116:1-5 (agreeing that TVT and TVT-O are the same mesh). Indeed, he readily acknowledges that polypropylene "is the safest style of synthetic mesh we can use." *Id.* at 103:14-104:8.

The primary focus of his design-defect opinion then is his criticism of the surgical *technique* used to implant TVT-O. Ex. B, Kohli Report at 8-9 (supporting design defect opinion through criticism of "[v]arious aspects of the TVT-O technique"); *see also id.* at 22-25 (supporting design defect theory through opinion that TVT-O "inside-out" technique is more complex and difficult than TOT "outside-in" technique); *id.* at 28 (testifying that pain seen less frequently with retropubic and "outside-in" procedures); *id.* at 32 (claiming TVT-O helical needles make placement "extremely difficult").

Dr. Kohli does not offer any opinion as to any alternative feasible *designs* for TVT-O. He simply claims that safer *surgical* alternatives exist, including surgery to harvest native tissue. *Id.* at 10 (referring generally to "safer alternatives"); *id.* at 37 (opining that there are "safer surgical alternatives" such as the Burch retropubic procedure and autologous fascia—*i.e.*, native tissue—and that TVT-O should not have been marketed because "better procedures" were available); *id.* at 38 ("[T]he risks of the Gynecare TVT-O outweigh the benefits especially when alternative *surgical options* are available" (emphasis added)); Ex. C, Kohli 3/21/16 Dep. Tr. 104:21-105:4 (claiming safer alternatives to TVT-O are "non-mesh procedures" and "retropubic TVT" procedure).

His opinions, however, are inadmissible because a *medical device* is not defective in design simply because alternative *surgical procedures* may exist. In *Talley v. Danek Med., Inc.*, 179 F.3d 154, 162 (4th Cir. 1999), for example, the Fourth Circuit affirmed summary judgment for the defendant where the plaintiff's expert offered the same type of design-defect opinion as Dr. Kohli offers here. The expert in *Talley* claimed that the defendant's spinal-fusion device was defective because there were more successful alternative spinal fusion procedures that did not use spinal-fixation devices. *Id*. The Court properly concluded, however, that the expert's opinion "did not indicate any design flaw," but rather "it questioned the medical judgment of doctors who use spinal fixation devices in surgery." *Id*. Further, the Court reasoned that "[w]hile such an opinion might be relevant in a malpractice suit against a doctor, it is irrelevant in a suit against the product manufacturer." *Id*.

Courts around the country have similarly found surgical alternatives irrelevant to design-defect claims. *See, e.g.*, *Schmidt v. C.R. Bard, Inc.*, No. 2:11-cv-00978, 2013 WL 3802804, at *2 (D. Nev. July 22, 2013) (granting summary judgment to defendant because "[t]he fact that an

alternative method of surgical hernia repair was potentially available does not support[] Plaintiff'[s] design defect claim"); *Bogle v. Sofamor Danek Grp., Inc.*, No. 95-8646, 1999 WL 1132313, at *4 (S.D. Fla. Apr. 9, 1999) (emphasizing that the expert's "testimony fails to identify any particular defect *with the product*. He testified that the design of the screw made it difficult to utilize, that only the most skilled surgeons could implant it with any degree of success, that if he were designing a pedicle screw he would design it differently . . . . The Court is not persuaded that such testimony identifies a defect in the product, rather, at the most it identifies that it is a product reserved to a top-rate surgeon" (emphasis added)); *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 256 (E.D.N.Y. 1999) (granting summary judgment on design-defect claim where expert focused on surgical technique and noninstrumental spinal repair, not a defect in the product itself).

At bottom, alternative *surgical techniques*, including those using native tissue, are not alternative feasible *designs*. *See, e.g.*, *Linsley v. C.R. Bard, Inc.*, No. 98-2007, 2000 WL 343358, at *3 (E.D. La. Mar. 30, 2000) (granting summary judgment where expert had "merely show[n] that . . . there existed 'alternative techniques' for repairing a ventral hernia using Marlex Mesh, and not . . . an alternative design"); *Schmidt*, 2013 WL 3802804, at *2 ("[N]on-mesh repair is not an alternative design and does not meet Plaintiff's burden to support [a design-defect claim]."); *Theriot v. Danek Med., Inc.*, 168 F.3d 253, 256 (5th Cir. 1999) (finding surgical alternatives that do not use pedicle screws cannot be considered "alternative designs"); *Hornbeck v. Danek Med., Inc.*, No. 99-30966, 2000 WL 1028981, at *1 (5th Cir. July 5, 2000), 226 F.3d 641 (Table) (noting that "alternative methods of treatment are not alternative designs"); *Toll v. Smith & Nephew Richards, Inc.*, Nos. 95-442 & 97-1057, 1998 WL 398062, at *2 (E.D. La. July 14, 1998) ("Plaintiffs have only suggested alternative methods of [surgery] which utilize the

System's already existing components; plaintiffs have not established an alternative design to the System. The component parts of the System remain the same.").

Ethicon acknowledges the Court's decision in its September 1, 2016 Memorandum Opinion and Order regarding Dr. Kohli to defer ruling on this same issue until it can be assessed in context during trial. *See In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL 2372, (at 6-7 (MDL Dkt. 2709) (S.D.W. Va. Sept. 1, 2016) (Kohli Order). Recognizing that the Court may again defer ruling on the issue, Ethicon maintains that, to the extent Dr. Kohli's design-defect opinions are based on *alternative surgical procedures*, they do not, and cannot, support Plaintiffs' design-defect claims and thus should be excluded.[1]

II. Dr. Kohli's opinion concerning TVT-O's relative complication rate should be excluded because it is unreliable and irrelevant.

Dr. Kohli will testify that *other* polypropylene mesh devices "like" TVT-O are associated with complications not seen, or seen less frequently, compared to nonmesh procedures—and then simply concludes with no explanation that "[i]n the case of the TVT-O, the rates and severity of these complications, particularly pain are unacceptably high." Ex. B, Kohli Report at 26.

The Court has previously excluded expert testimony concerning complication rates when the expert did not explain his methodology, including its most recent decision addressing such opinions from Dr. Kohli. *See* Kohli Order (MDL Dkt. 2709) at 6 (excluding Dr. Kohli's opinion that the TVT-O complication rate is "unacceptably high," for lack of scientific support or methodology); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 721 (S.D.W. Va. 2014). That is

[1] Dr. Kohli's criticisms of the TVT-O surgical technique are in fact set forth in the "Design Defect" section of his expert report. *See* Ex. B, Kohli Report at 20-26.

precisely the case here, where Dr. Kohli's expert report provides the exact same opinion as that previously excluded by the Court. Ex. B, Kohli Report at 26.

Although Dr. Kohli cites several articles to support his conclusory opinion, none of them actually discuss TVT-O. *See* Ex. B, Kohli Report at 26, n.17; Ex. D, Articles. With no explanation or detail, Dr. Kohli simply extrapolates a conclusion about TVT-O from literature about other products because he thinks they are "like" TVT-O, which is to say nothing more than a Ford Mustang is "like" a Chevrolet Malibu because they are both automobiles. Indeed, Dr. Kohli mainly cites review articles discussing complications associated with many other, often unidentified, mesh products implanted through multiple different surgical techniques. Ex. D, Articles. None of these articles provide complication rates for TVT-O, let alone in a systematic or validated manner to which they can accurately be compared to "nonmesh surgical treatments." *Id*. Nor does Dr. Kohli provide support for his opinion that "nonmesh surgical treatments" have lower complication rates than TVT-O. *See* Ex. B, Kohli Report at 26.

Even if it were proper to extrapolate data for other products to TVT-O, Dr. Kohli does not identify what data he is relying on in these articles that would demonstrate the reliability of his opinion that "nonmesh surgical treatments" have lower complication rates. Indeed, he does not even identify a "nonmesh" complication rate. Dr. Kohli has not done any testing, statistical analyses, or meta-analyses of TVT-O. Ex. C, Kohli 3/21/16 Dep. Tr. 24:22-23, 121:10-18. Nor does he claim to be a biostatistician or have the credentials necessary to qualify as an expert in epidemiology. *Id*. at 121:19-23. Because his complication-rate-comparison opinion is unsupported, it should be excluded as unreliable.

In its prior Order concerning Dr. Kohli's complication-rate opinions, the Court reiterated its prior rulings that lack of comparison studies between two devices does not itself render an

expert's an expert's complication-rate opinions unreliable. Kohli Order (MDL Dkt. 2709) at 6. Ethicon does not challenge this point. Rather, the problem with Dr. Kohli's complication-rate comparison is that—regardless of the type of device at issue—he has offered no opinion or methodology as to what those other devices' or procedures' complication rates actually are, let alone explain how the articles he cited demonstrate a validated overall complication rate with which to compare to TVT-O. Thus, he should be precluded from opining not only that the complication rate for TVT-O is "unacceptably high," but also that the complication rate for other devices is "acceptable" or "lower" than TVT-O.

His complication-rate opinion should also be excluded because it is irrelevant. Because nonmesh *procedures* cannot serve as feasible alternative *product designs*, those procedures' complication rates are not appropriately compared to TVT-O to prove defect. Accordingly, testimony about the relative complication rates of TVT-O and nonmesh procedures—for purposes of opining that TVT-O is defective[2]—should be excluded for the same reasons already discussed.

Last, Dr. Kohli provides no objective basis for what constitutes an acceptable versus unacceptable complication rate. Thus, his "unacceptably high" complication-rate opinion appears to be no more than *ipse dixit*, or a personal opinion, and should be excluded on that basis. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997); Kohli Order (MDL Dkt. 2709) at 6 (excluding Dr. Kohli's complication rate opinion as *ipse dixit*); *Sanchez v. Boston Scientific Corp*., No. 2:12-cv-05762, 2014 WL 4851989, at *31-32 (S.D.W. Va. Sept. 29, 2014) (finding that subjective and

[2] Dr. Kohli intends to offer these opinions precisely to prove that TVT-O is defective in design, as that is the section of his report in which the opinion is provided. *See* Ex. B, Kohli Report at 20-26.

conclusory approach to opinion demonstrated mere speculation and personal belief warranting exclusion of the opinion as unreliable).

III. Dr. Kohli's clinical-studies-prediction opinion should be excluded as unreliable.

Dr. Kohli will testify that "if clinical studies had been performed prior to launch, the flaws in the device would have been demonstrated." Ex. B, Kohli Report at 9. According to him, "if clinical trials had been performed, the outcomes and complications in the TVT-O design would have become apparent." *Id*. at 29. Ethicon anticipates that Plaintiffs will withdraw these opinions, as they did in the Wave 1 and Wave 2 briefing cycles. *See* Pls.' Unopposed Mot. to Strike & Replace Doc. (MDL Dkt. 2178) at 9 (Wave 1); Pls.' Notice of Adoption of Prior Daubert Resp. (MDL Dkt. 2510) at 1 (incorporating MDL Dkt. 2178 for Wave 2). If the opinions are not withdrawn, however, the basis for Ethicon's motion to exclude these opinions is provided below.

Dr. Kohli provides no details concerning these hypothetical clinical studies, including their design, feasibility, participants, duration, comparator products, or the like. He makes no mention of having professional expertise in clinical-study design for medical devices. And he admits that he neither participated in any actual TVT-O clinical studies nor published any peer-reviewed studies involving TVT-O. Ex. C, Kohli 3/21/16 Dep. Tr. 53:21-54:3.

Rather, Dr. Kohli assumes—with no basis—that all currently known complications and "flaws" in a medical device would be predicted in hypothetical prior clinical studies. This opinion should be excluded because it is nothing more than his subjective belief and unsupported speculation. *Daubert*, 509 U.S. at 590 ("[T]he word 'knowledge' connotes more than subjective belief or unsupported speculation."); *In re C.R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:11-CV-00195, 2013 WL 3821280, at *2 (S.D.W. Va. July 23, 2013) (noting that without

evidence as to what a clinical study would have shown, the failure to test is merely speculative of what the manufacturer "should have known"); *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 631 (S.D.W. Va. 2013) (excluding Dr. Kessler's opinion that Bard should have conducted clinical trials as personal opinion); *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2009 WL 1357236, at *2 (E.D.N.Y. May 12, 2009) ("Subjective or intuitive guesswork, as well as testimony that is insufficiently connected to the facts of the case, are grounds for rejection of a proffered expert's testimony.").

IV. Dr. Kohli's opinion about TVT-O's appropriateness for certain patient populations should be excluded as unreliable and unhelpful to the jury.

Dr. Kohli will testify that Ethicon marketed TVT-O as a "one-size-fits-all" device for all patients, even though company documents and the medical literature indicated certain patient populations (*e.g.*, obese women, "sportive" women, women of different ethnicities, diabetics, and smokers) were at higher risk for complications or had lower success outcomes. Ex. B, Kohli Report at 35. He will further testify that doctors were not provided this information. *Id*. He provides no support for these statements—including any citation to the company documents and medical literature that he mentions. Nor does he claim that this unspecified evidence—even if he had provided it—demonstrates that this alleged increased risk for complications or poor outcomes is unique to TVT-O as opposed to other mesh devices.

Devoid of support, this opinion is unreliable and should be excluded from trial. Indeed, this exact opinion was excluded by the Court in its September 1 Order. *See* Kohli Order (MDL Dkt. 2709) at 7 (excluding the opinion as *ipse dixit*); *see also Edwards*, 2014 WL 3361923, at *10 (excluding essentially the same opinion offered by Dr. Rosenzweig due to similar lack of evidence). Accordingly, Dr. Kohli's opinion should be excluded here too.

V. Dr. Kohli's opinions regarding the competency of other physicians should be excluded as irrelevant.

This Court has already ruled that opinions regarding the competence of other physicians are irrelevant. *Edwards*, 2014 WL 3361923, at *17. In so ruling, the Court examined testimony from the plaintiff's expert and precluded the expert from testifying to the effect that: (1) it is difficult to learn the surgical technique to implant TVT-O, (2) it is easy to misguide the trocars, (3) Ethicon trivialized the learning curve and potential complications, and (4) surgeons with inadequate skill and experience performed these surgeries. *Id*.

Dr. Kohli intends to offer nearly identical opinions, including these:

- The inside-out approach and complex helical needles render the TVT-O implant more difficult to perform. Ex. B, Kohli Report at 9.
- The instrumentation made it difficult to insert TVT-O into the correct space. *Id*. at 25 (discussing example of "highly experienced urogynecologist," May Wakamatsu).
- The unique design of TVT-O helical needles and required trajectory makes placement extremely difficult. *Id*. at 32 (discussing personal experiences training surgeons and literature reporting various physicians' experiences with device placement).

The Court has already determined that such opinions offered by Dr. Kohli are excluded. *See* Kohli Order (MDL Dkt. 2709) at 7. To the extent Plaintiffs intend to have Dr. Kohli offer them in the Wave 3 cases, they should likewise again be excluded.

VI. Dr. Kohli's opinions on Ethicon's knowledge, motives, and intentions, and his narrative review of corporate documents, are inadmissible.

The Court has repeatedly held that it will not permit expert testimony on "Ethicon's knowledge, state of mind, or other matters related to corporate conduct and ethics" because these matters "are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury." *Lewis v. Ethicon, Inc.*, No. 2:12-CV-4301, 2014 WL 186872, at *6 (S.D.W. Va. Jan. 15, 2014), *reconsideration denied sub nom*. *In re Ethicon, Inc.*, No. 2:12-CV-4301,

2014 WL 457544 (S.D.W. Va. Feb. 3, 2014); *see also, e.g.*, *Wise v. C.R. Bard, Inc.*, No. 2:12-CV-01378, 2015 WL 521202, at *4 (S.D.W. Va. Feb. 7, 2015); *Huskey*, 29 F. Supp. 3d at 703; *In re Ethicon, Inc.*, 2014 WL 186872, at *6, *21; *In re C. R. Bard*, 948 F. Supp. 2d at 611, 629. In *Huskey*, the Court also excluded expert opinions that offer "simply a narrative review of corporate documents," holding that such "opinions" are not helpful to the jury. *Huskey*, 29 F. Supp. 3d at 706; *see also Sanchez*, 2014 WL 4851989, at *32 (same); *Edwards*, 2014 WL 3361923, at *10 (finding expert's explanation of company documents not helpful; the jury is capable of reading and interpreting the documents itself).

In its September 1 Order specifically addressing the opinions of Dr. Kohli, the Court reiterated its prior rulings, and again held that state-of-mind opinions, and parroting of corporate documents, are prohibited. *See* Kohli Order (MDL Dkt. 2709) at 10-11. Dr. Kohli, however, repeatedly offers opinions throughout his expert report concerning Ethicon's knowledge, motives, and intentions concerning the development and marketing of TVT-O. Similarly, he provides several pages of narrative review of Ethicon's documents, including his interpretations of the witnesses' states of mind. Despite the Court's rulings that this testimony is improper, Plaintiffs have refused to withdraw these opinions, claiming they are "more than a 'narrative review' of corporate documents." *See* Pls.' Unopposed Mot. to Strike & Replace Doc. (MDL Dkt. 2178) at 12. Consistent with the Court's prior rulings, Dr. Kohli's corporate-knowledge and corporate-motive opinions should be excluded in their entirety, including, but not limited to, the following opinions:

- Dr. Kohli's "sense" that introduction of TVT-O "was a reactionary and compensatory move to address the competition from the traditional TOT (outside-in) sling procedure." Ex. B, Kohli Report at 5.

- Dr. Kohli's "feeling" that "Gynecare introduced the [TVT-O 'inside-out'] procedure to reduce the erosion of TVT share, seem 'more innovative' and also avoid patent/licensing issues." *Id*. at 5, 20.

- The TVT-O surgical technique was "introduced for commercial vs clinical reasons as a response to the TOT sling and its erosion of the TVT market share . . . ." *Id*. at 8-9.

- Ethicon "'rushed to market'" TVT-O. *Id*. at 9; *see also id*. at 21.

- Ethicon marketed TVT-O "indiscriminately" to physicians and patients. *Id*. at 9.

- Ethicon "felt their dominant position backed by history in TVT was immune to sales pressure." *Id*. at 20.

- Comment that TVT-O inventor "had strong financial incentive [to] show his product worked so it could be acquired for millions of dollars." *Id*. at 21.

- TVT-O "was released in response to competitive pressures . . . ." *Id*. at 22,

- Ethicon did not perform testing relating to transient leg pain "because Ethicon did not take the time it would require." *Id*. at 29.

- Narrative review of company documents relating to early TVT-O marketing and development. *Id*. at 20-22.

- Narrative review of "'TVT Key Selling Points Versus Competitors'" document. *Id*. at 25.

- Narrative review of documents discussing pain complications. *Id*. at 28-29.

- Narrative review of documents discussing "aggressive development course." *Id*. at 29.

- Narrative review of documents relating to post-operative pain. *Id*. at 29-32.

- Narrative review of documents relating to physician training and marketing. *Id*. at 33-34.

- Narrative review of documents relating to the IFU for the TVT-O. *Id*. at 36.

All of these opinions should be excluded.

CONCLUSION

For the foregoing reasons, Ethicon asks this Court to grant its motion and exclude or limit Dr. Kohli's general-causation opinions as outlined above.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on September 19, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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